



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
---------------	-------------	----------------------	---------------------

08/308,219 09/19/94 ALIZON

18M2/0206

FINNEGAN HENDERSON FARABOW
GARRETT AND DUNNER
1300 I STREET NW
WASHINGTON DC 20005-3315

M 3495, 001020
EXAMINER

RAILEY, J

ART UNIT PAPER NUMBER

17

1804

DATE MAILED:

02/06/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☒ Notice of References Cited by Examiner, PTO-892.
- ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
- ☒ Notice of Art Cited by Applicant, PTO-1449.
- ☐ Notice of Informal Patent Application, PTO-152.
- ☐ Information on How to Effect Drawing Changes, PTO-1474.
- ☐ _____

Part II SUMMARY OF ACTION

- ☒ Claims 11 AND 12 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
- ☐ Claims _____ have been cancelled.
- ☐ Claims _____ are allowed.
- ☒ Claims 11 AND 12 are rejected.
- ☐ Claims _____ are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.
- ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
- ☐ Formal drawings are required in response to this Office action.
- ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
- ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
- ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
- ☒ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☒ been received ☐ not been received.
☒ been filed in parent application, serial no. 07/158,652; filed on 2/22/88.
- ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
- ☐ Other

EXAMINER'S ACTION

Serial No. 08/308,219
Art Unit 1804

-2-

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing adequately to teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Applicant claims a specific nucleotide sequences which is the LTR region of HIV-1. The disclosed utility of this nucleic acid is as a probe "in hybridization assays to detect the presence of nucleic acid of HIV-1 in a biological sample. See applicant's response, paper No. 11, received 16 August 1994, page 2. Applicant's response suggests that the reference by Hahn et al. of record does not teach cross-hybridization between nucleic acids corresponding to the complete LTR of HIV-1, HTLV-I, and HTLV-II. However, applicant's specification fails to describe hybridization assays which would allow distinction between HIV-1 and other lentiviruses, such as HIV-2 or SIV (STLV-III). The specification fails to teach how to use the disclosed nucleic acid sequence as a probe to detect HIV-1 specifically in a biological

Serial No. 08/308,219
Art Unit 1804

-3-

sample. Applicant is provided with two references: Guo et al. [AIDS Research and Human Retroviruses 3(2):177-185 (1987)] and Clavel et al. [Nature 324:691-695 (1986)]. Guo et al. teach the structure of the LTR of STLV-III (SIV). As noted in the abstract, overall the LTR of SIV is 45% homologous with that of HIV-1. Clavel et al. shows in Figure 3 that the HIV-1 fragment probe which is the 3'LTR hybridizes well to HIV-2 under non-stringent conditions. Consequently, the HIV-1 LTR does cross-hybridize with other lentiviruses. Applicant's specification fails to set forth the hybridization and washing conditions under which the claimed nucleic acid probe would be useful to distinguish HIV-1 from other lentiviruses in a "biological sample." Applicant's response at page 6 notes that the specification at page 14, lines 29-32 suggests that hybridization assays using nucleic acid probes "have already been developed for Hepatitis B virus." It is not evident, however, what hybridization conditions are set forth for Hepatitis B virus, nor whether they are applicable for use with applicant's probe as claimed. The specification fails to point out what those hybridization conditions are, and that these conditions detect HIV-1 specifically in a given "biological sample."

Claims 11 and 12 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Serial No. 08/308,219
Art Unit 1804

-4-

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. F. Railey, whose telephone number is (703) 308-0281. The examiner can normally be reached on Monday-Thursday from 7:30 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jacqueline Stone, can be reached at (703) 308-0254. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Johnny F. Railey II, Ph.D.
January 25, 1995

JACQUELINE STONE
PRIMARY EXAMINER
ART UNIT 1804